National Kidney Cancer Association

Suite 203
1234 Sherman Ave.
Evanston, Il 60202-1375
tel: 847-332-1051
fax: 847-332-2978

4074 '98 JUL 24 A10:18

July 21, 1998

Dockets Management Branch (HFA-305)
United States Food & Drug Administration
Department of HHS, Room 123
12420 Park Lawn
Rockville, MD 20857

To Whom It May Concern:

The Kidney Cancer Association ("KCA" or "the Association") is pleased to provide its comments on the FDA's proposed rule to implement the dissemination provisions of Section 401 of the FDA Modernization Act of 1997 ("FDAMA"). These written comments will supplement those delivered orally at the Public Meeting held on July 8, 1998.

The Association believes that the FDA staff has acted diligently and in good faith in writing the proposed rule. However, we believe that some revisions are needed in the following areas:

1. The proposed rule too narrowly restricts the definition of peer-reviewed journal articles. Section 401's language is clear. Such articles are to be "about a clinical investigation...that would be considered scientifically sound by experts." The proposed rule significantly expands this, by requiring a "reasonably comprehensive presentation of the study design, conduct, data, analyses and conclusions..." The Association believes that this could be construed as imposing a burdensome level of detail.

2. The proposed rule restricts or prevents the dissemination of reference texts. A result of the narrowness of the proposed rule is the seeming exclusion of reference texts. Such texts do not present reports on individual clinical investigations in the "reasonably comprehensive manner" required by the proposed rule. As a result, they would be excluded. This result appears to thwart the clear intent of Congress.

Respectfully submitted,

Carl F. Dixon
President & Executive Director

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